

REMARKS

The above-referenced application has been reviewed in light of the Office Action mailed March 21, 2005. It is respectfully submitted that the claims pending in the application do not introduce new subject matter, are fully supported by the specification, and are patentable over the prior art. Prompt and favorable consideration of these claims is earnestly sought.

The Office Action rejected claims 2-5, 7-9, and 11-13 under 35 U.S.C. § 112, first paragraph and asserted that they recited subject matter not adequately described in the detailed description. In particular, the Office Action asserted that the written description did not disclose the first aperture of the first inflatable member being capable of "slidably receiving" a surgical instrument and further stated that the instrument is capable of contacting and sliding on the inner surface of the inner lumen, but that such contact appears to prevent the instrument from contacting the surface which forms the aperture of the first inflatable member. Further still, the Office Action rejected claims 2-5, 7-9, and 11-13 under 35 U.S.C. § 112, second paragraph as being indefinite for the same reasons. The Applicant respectfully disagrees since claim 2 recites that "the first aperture and the first bore being configured and dimensioned for slidably receiving a surgical instrument therethrough" and does not recite that the surgical instrument contacts either the first bore or the first aperture as construed in the Office Action. Support for the language recited in claim 2 can be found, at least, on pages 19-20 of the specification and in Figure 13. Therefore, it is respectfully submitted that claims 2-5, 7-9, and 11-13 are fully supported by the specification and that the rejection of the Office Action has been overcome.

The Office Action rejected claims 2, 5, 7-9, and 13 under 35 U.S.C. § 103 (a) as being unpatentable over U.S. Patent No. 4,655,746 to Daniels et al. (the '746 patent) in view of U.S. Patent No. 5,180,367 to Kontos et al. (the '367 patent). According to the Office Action, the '746 patent discloses a first tubular member 68 having an open proximal end, a first inflatable member 72, a second tubular member 16 having open proximal and distal ends defining a bore 18 therethrough and a second inflatable member 30. The Office Action stated that the '746 patent is deficient in that it fails to disclose the first inflatable member 72 and the first tubular member 68 having an open distal end and acknowledged that guide wire 74 plugs the distal end of the first inflatable member 72. The Office Action stated that the '367 patent discloses that the tubular member of the inner, pilot balloon can have an open distal end so that it can slidably receive the guide wire and that it would have been obvious to make the distal end of the first inflatable member 72 and the first tubular member 68 of the '746 patent open as disclosed in the '367 patent.

Claim 2 recites, *inter alia*, an apparatus including a first inflatable member having a first aperture, a second inflatable member having a second aperture wherein "the first aperture and the first bore being configured and dimensioned for slidably receiving a surgical instrument therethrough."

The '746 patent relates to a catheter device for delivering fluids to a target region in a vessel of a patient by isolating the target region using two inflatable balloons. Specifically, the '746 patent discloses that a guide wire 74 is disposed in the interior of inflatable balloon 72 and is attached to a flexible spring 76 at the distal end of the inflatable balloon. As acknowledged in

the Office Action, the distal end of the inflatable balloon 72 is plugged by guide wire 74 and more specifically by flexible spring 76 (see Figure 5 reproduced below). According to the '746 patent, the guide wire 74 is used to guide the tube 68 and inflatable balloon 72 into a blood vessel (the '746 patent at Column 6, lines 28-50) through tube 16. The '367 patent discloses a tubular member having an open distal end so that a guide wire may extend through the open distal end.

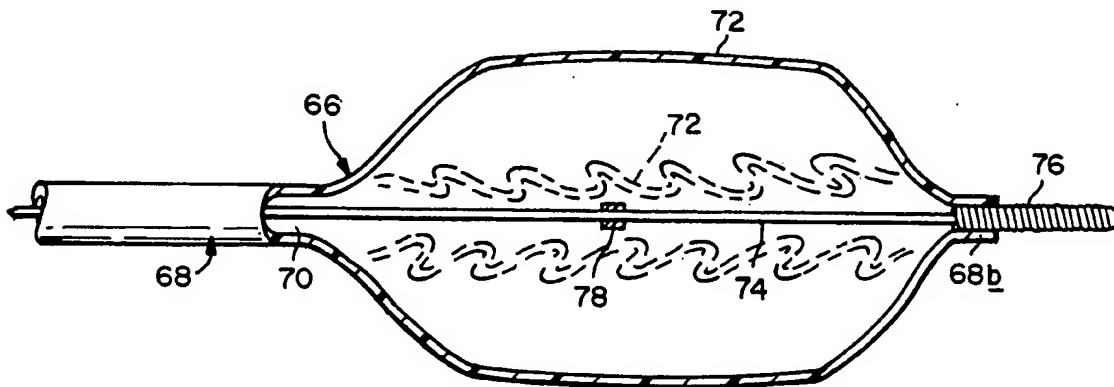


FIG. 5.

Modifying the device disclosed in the '746 patent to have an open distal end as disclosed in the '367 patent as suggested in the Office Action does not result in a device having, *inter alia*, a first inflatable member having a first aperture, a second inflatable member having a second aperture wherein "the first aperture and the first bore being configured and dimensioned for slidably receiving a surgical instrument therethrough" as recited in independent claim 2. In particular, the '746 patent discloses that the guide wire is attached to the flexible spring at the distal end of the inflatable balloon for guiding and moving the inflatable balloon so as to position

the inflatable balloon in the target region of a vessel. Providing the device of the '746 patent with an open distal end as disclosed in the '367 patent, and suggested in the Office Action, would necessitate the removal of the flexible spring and, therefore, remove the attachment point for the guide wire to the inflatable balloon and render the device of the '467 patent incapable of being maneuvered from the proximal end of the device as specifically disclosed in the '467 patent.

Additionally, the '746 patent does not disclose or suggest alternative structures for maneuvering or positioning the inflatable balloon other than attaching the guide wire to the flexible spring at the distal end of the inflatable balloon so that the inflatable balloon is positionable from the proximal end of the device (the '746 patent at Column 6, lines 28-50). Therefore, providing the inflatable balloon of the '746 patent with an open distal end as disclosed in the '367 patent would be contrary to the disclosure of the '746 patent, since the '746 patent specifically discloses that the guide wire is attached to the flexible spring at the distal end of the inflatable balloon (the '746 patent at Column 4, lines 52-62) and is used to position the inflatable balloon when locating the inflatable balloon in the target region of the vessel (the '746 patent at Column 6, lines 28-50). Therefore, it is respectfully submitted that independent claim 2 is not suggested by the combination of the '746 patent in view of the '367 patent and the rejection of the Office Action has been overcome. Claims 5, 7-9, and 13 depend directly or indirectly from independent claim 2 and it is respectfully submitted that the rejection of these claims has been overcome as well.

Claims 3 and 4 were rejected in the Office Action under 35 U.S.C. § 103 (a) as being unpatentable over the '746 patent in view of the '367 patent and further in view of U.S. Patent No. 4,981,478 to Evard et al (the '478 patent). The Office Action stated that the '746 patent fails to disclose an inner member defining an annular space with the first tubular member, but that the '478 patent discloses that a balloon catheter can be constructed with an inner tubular member 13 and an outer tubular member 11 with an annular space therebetween. Further still, the Office Action stated that it would have been obvious to construct the first tubular member of the '746 patent to so it would also include this feature.

Claims 3 and 4 depend directly or indirectly from independent claim 2. As discussed hereinabove, the device recited in independent claim 2 is not suggested by the combination of the '746 patent in view of the '367 patent. Adding the annular space between inner and outer tubular members as disclosed in the '478 patent, as suggested by the Office Action, does not overcome the deficiencies of the '746 patent in view of the '367 patent and does not result in a device having, *inter alia*, a first inflatable member having a first aperture, a second inflatable member having a second aperture wherein "the first aperture and the first bore being configured and dimensioned for slidably receiving a surgical instrument therethrough" as recited in independent claim 2. Therefore, it is respectfully submitted that claims 3 and 4 are not suggested by the combination of the '746 patent in view of the '367 patent and further in view of the '478 patent, and the rejection of the Office Action has been overcome.

Claims 11 and 12 stand rejected under 35 U.S.C. § 103 (a) as being unpatentable over the '746 patent in view of the '367 patent and further in view of U.S. Patent No. 4,690,140 to Mecca (the '140 patent). According to the Office Action, the distal end of the first tubular member 68 of the '746 patent, as modified hereinabove to include the asserted advantages of the '367 patent, would inherently be capable of receiving an endoscope or a laparoscopic instrument.

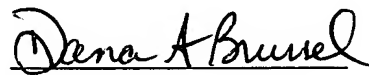
Claims 11 and 12 depend directly from independent claim 2. As discussed hereinabove, the device recited in independent claim 2 is not suggested by the combination of the '746 patent in view of the '367 patent. Adding the surgical instrument as disclosed in the '140 patent, as suggested by the Office Action, does not overcome the deficiencies of the '746 patent in view of the '367 patent and does not result in a device having, *inter alia*, a first inflatable member having a first aperture, a second inflatable member having a second aperture wherein "the first aperture and the first bore being configured and dimensioned for slidably receiving a surgical instrument therethrough" as recited in independent claim 2. Therefore, it is respectfully submitted that claims 11 and 12 are not suggested by the combination of the '746 patent in view of the '367 patent and further in view of the '140 patent, and the rejection of the Office Action has been overcome.

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Amdt. dated June 21, 2005
Reply to Office Action Mailed March 21, 2005

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims pending in the application, namely claims 2-5, 7-9, and 11-13, are in condition for allowance. Should the Examiner desire a telephonic interview to resolve any outstanding matters, he is sincerely invited to contact the undersigned at (631) 501-5713.

Respectfully submitted,

Carter, DeLuca, Farrell & Schmidt, LLP
445 Broad Hollow Road - Suite 225
Melville, New York 11747
Tel.: (631) 501-5713
Fax: (631) 501-3526


Dana A. Brussel
Reg. No. 45,717
Attorney for Applicants

Send correspondence to:
Chief Patent Counsel
Tyco Healthcare Group
150 Glover Avenue
Norwalk, CT 06856